further view of "The ASM Handbook Volume 2"; claim 20 was rejected under 35 U.S.C. § 103(a) as unpatentable over Fischell in view of Steinemann and further in view of Scott et al., U.S. Patent No. 5,383,928 ("Scott"); claim 20 was further rejected under 35 U.S.C. § 103(a) as unpatentable over Lau in view of Lenning and further in view of Scott; claim 21 was rejected under 35 U.S.C. § 103(a) as unpatentable over Fischell in view of Steinemann and further in view of Wiktor, U.S. Patent No. 5,653,727 ("Wiktor"); and claim 21 was further rejected under 35 U.S.C. § 103(a) as unpatentable over Lau in view of Lenning and further in view of Wiktor. As explained below, all of the currently pending rejections under 35 U.S.C. § 103(a) are in error.

The rejection of claims 1-6, 9, 10, 12, 14, 15 and 19 as unpatentable over Fischell in view of Steinemann is in error. Fischell, the primary reference, discloses a structural design for an expandable stent, which can be made of "stainless steel, tantalum, titanium, or a shape memory metal such as Nitinol." (Fischell, col. 3, lines 51-53). Fischell further discloses the following:

> For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings with could be formed from gold with is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively non-thrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

(Fischell, col. 3, lines 11-19). Fischell fails to disclose an alloy for the stent having the composition set forth in claims 1-6, 9, 10, 12, 14, 15 and 19.

The Examiner addresses this deficiency by using the claimed alloys as a reference point. Proceeding backwards he then sets out to find a reference that discloses an alloy having a composition similar to that of the claimed alloys that he can substitute for Fischell's alloy. The Examiner finds one example of an alloy in Steinemann that meets the requirements of independent claim 1. In making the argument for the combination, however, the Examiner fails to consider the knowledge and level of skill of one having ordinary skill in the art and the teachings of the cited references, and he fails put forth a reason that would have actually prompted one having ordinary skill in the art to use the alloy of Steinemann to make the stent of Fischell. As the Supreme Court recently explained, "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated

reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). In that regard, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* The mere fact that the prior art reference could be modified does not satisfy the requirements for a finding of obviousness. *In re Laskowski*, 871 F.2d 115, 117 (Fed. Cir. 1989); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). Accordingly, the rejection is improper and should be withdrawn.

In making the rejection, the Examiner states that it would have been obvious to make the stent disclosed by Fischell out of the alloy disclosed by Steinemann "in order to combine corrosion resistance, compatibility, and high strength for uses in surgery (balloon expandable stent), as disclosed by Steinemann." This argument, however, fails to consider that one having ordinary skill in the art would recognize that titanium is already a sufficiently corrosion resistant and compatible material for use in stents and that the "high strength" disclosed by Steinemann is inapplicable to stents. Steinemann even recognizes that that titanium is already sufficiently biocompatible. (See Steinemann, col. 1, lines 22-32). Instead of seeking to find a replacement alloy for stent applications, Steinemann was concerned with developing an alloy that "permits functional loading of the bone bridged by the implant" and thus does not result in the "dangerous weakening of the bone substance or decalcification and further fractures." (Steinemann, col. 1, lines 52-55). One having ordinary skill in the art of stent design would recognize that this "high strength" of the Steinemann alloy is irrelevant to stent design because stents are not implanted within a bone. Because the Examiner's alleged reason for using the alloy of Steinemann to produce the stent of Fischell are not the types of reasons that would actually cause one having ordinary skill in the art to use the alloy of Steinemann to make a balloon-expandable stent, the Examiner's asserted reasons are legally insufficient.

The Examiner's argument also fails to consider that balloon-expandable stents require various combinations of physical properties. For example, a balloon-expandable stent should be able to withstand deformation under the normal physiological conditions, but undergo large permanent deformations when being implanted. Accordingly, not every type of implant material

is suitable for producing a balloon-expandable stent. The disclosure of using the Steinemann alloy in a bone screw does not suggest that it would have the host of physical properties required for a balloon-expandable stent. An artisan having ordinary skill in the art of stent design would realize that different alloys have different physical qualities and that balloon-expandable stents require a host of particular physical properties that would not necessarily be met by the alloy disclosed by Steinemann. Accordingly, an artisan having ordinary skill in the art at the time of invention would not have found it obvious to replace the titanium used in Fischell's stent with the alloy of Steinemann.

The rejection of claims 1-6, 11-12, 14-15, 19, and 41 as unpatentable over Lau in view of Lenning is also in error. Lau, the primary reference, discloses an expandable stent and a method of making it from a single length of tubing. (Lau, Abstract). Lau discloses that it can be made of "suitable biocompatible material such as stainless steel, tantalum, titanium, superelastic NiTi alloys and even high strength thermoplastic polymers." (Lau, col. 7, lines 5-7). Lau, however, fails to disclose an alloy for the stent having the composition set forth in claims 1-6, 11-12, 14-15, 19, and 41.

The Examiner addresses this deficiency by using the claimed alloys as a reference point. Proceeding backwards he then sets out to find a reference that discloses an alloy having a composition similar to that of the claimed alloys that he can substitute for Lau's alloy. The Examiner finds some alloys described in Lenning that meet the requirement of the alloys claimed in independent claims 1 and 41. Lenning, however, describes these alloys as having "the corrosion resistance of tantalum in their ability to withstand corrosive effects of solutions such as boiling hydrochloric, sulfuric, phosphoric or oxalic acids." (Lenning, col. 1, lines 20-25). This is not the type of environment experienced by a stent when implanted within a body lumen. Accordingly, one having ordinary skill in the art of stent design would not have found it obvious to substitute the alloy of Lenning for the materials disclosed by Lau.

In support of the combination, the Examiner asserts that Lau discloses that "the stent would be fabricated from titanium and/or tantalum alloy where corrosion resistance would be desired (Figures 2-4, col. 7, lines 5-8 and col. 8, line 30)." Applicant is unsure where the

Examiner finds support for this statement. The cited sections of the Lau reference do not support this statement. Lau does disclose the use of "stainless steel, titanium, tantalum, superelastic NiTi alloys and even high strength thermoplastic polymers" for making a stent, but does not recite the use of tantalum alloys or titanium alloys "where corrosion resistance would be desired." Furthermore, column 8, line 30 is part of a recipe for an acidic aqueous solution disclosed as being used to electrochemically polish the stents when making the stents. (Lenning, col. 8, lines 25-36). This passage does not suggest the use of titanium or tantalum alloys where corrosion resistance would be desired.

In making the rejection, the Examiner states that it would have been obvious to make the stent disclosed by Lau out of the alloy disclosed by Lenning "in order to improve corrosion resistance, as disclosed by Lenning." (Office Action, page 6, lines 21-22). This alleged reason, however, is again a reason that would not have actually prompted one having ordinary skill in the art to make the asserted combination. The argument fails to consider that one having ordinary skill in the art of stent design would know that there is no corrosion issue for stents made of the materials disclosed by Lau when implanted within a body lumen. Furthermore, Lenning discloses the need to have the alloy have corrosion resistance similar to tantalum, not superior to tantalum, for environments far more caustic than that experienced by a stent. (Lenning, col. 1, lines 20-25). The Examiner's argument also fails to consider that balloon-expandable stents require various combinations of physical properties. For example, a balloon-expandable stent should be able to withstand deformation under the normal physiological conditions, but undergo large permanent deformations when being implanted. Accordingly, not every type of implant material is suitable for producing a balloon-expandable stent. An artisan having ordinary skill in the art of stent design would realize that modifying an alloy would alter the physical qualities of that alloy and that balloon-expandable stents require a host of particular physical properties. Accordingly, the rejection is in error because the alleged reason would not have actually prompted one having ordinary skill in the art of stent design to make the balloon-expandable stent of Lau out of the Lenning alloy.

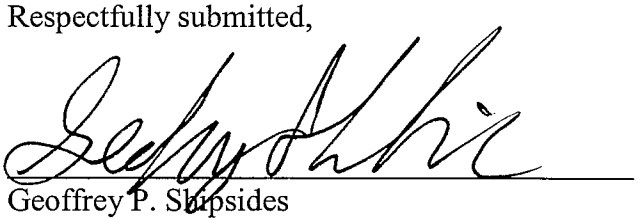
Furthermore, none of the additional secondary references of "The ASM Handbook Volume 2," Scott, and Wiktor further support the combinations of Fischell and Steinemann or Lau and Lenning. Accordingly, the rejections of dependent claims 16-18, 20, and 21 are also improper for the reasons given above.

Accordingly, each of the pending claims 1-6, 9-12, 14-21, and 41 defines patentable subject matter over the cited prior art. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 11/26/07



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